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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: Registration of Food Facilities Under the Public Health  
Security and Bioterrorism Preparedness and Response  
Act of 2002  
Docket No. 02N-0276

Gentlemen:

This letter is submitted on behalf of the National Alcohol Beverage Control Association (NABCA) in response to the Notice of Proposed Rulemaking concerning the registration of food facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 *Federal Register* 5378, February 3, 2003).

By way of background, NABCA is a trade association whose voting members are the 19 jurisdictions that directly control the distribution and sale of alcohol beverages pursuant to the Twenty-First Amendment to the Constitution of the United States through the operation of state-owned wholesale, and, in some cases, retail outlets. These jurisdictions are Alabama, Idaho, Iowa, Maine, Michigan, Mississippi, Montana, New Hampshire, North Carolina, Ohio, Oregon, Pennsylvania, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming and Montgomery County, MD. These states, and the facilities they operate, would be subject to the proposed facility registration requirement because the products distributed and sold by the states – i.e., distilled spirits and in some cases, wine and beer – are considered to be food products.

The proposed registration requirement, in the case of alcohol beverage distributors like NABCA's voting members, is duplicative. Under the Federal Alcohol Administration Act, which has been in effect since the repeal of Prohibition almost 70 years ago, no state or private company can engage in the production or distribution of distilled spirits or wine unless the organization first obtains a "basic permit" from the Alcohol and Tobacco Tax and Trade Bureau. (The TTB was formerly known as the Bureau of Alcohol, Tobacco and Firearms before its functions were reorganized earlier this year as a result of the enactment of legislation establishing the Department of Homeland Security.)

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Thus, the information being sought by FDA under the proposed registration requirement has already been submitted to and is maintained by the TTB. For that reason, NABCA urges FDA to reconsider its proposal as it applies to information on alcohol beverage facilities and to exempt those already-registered facilities from a duplicative paperwork burden.

Further, the proposed rule would impose a significant administrative burden on NABCA's voting member jurisdictions by requiring each covered facility to register separately with FDA.

To understand this burden, one must first understand the operational structure of these so-called "control" states. Several of the states only function as wholesalers, selling alcohol beverages to private retailers. Others operate both wholesale and state-owned retail facilities. In still other jurisdictions, there is a mix of state-operated and privately-operated retail stores, some of which function as "agency" outlets. More will be said later about these "agency" stores.

Regardless of the operational structure, however, the retail outlets not only sell to end-use consumers, but also provide alcohol beverages to other licensed facilities, such as restaurants, country clubs, taverns and bars. Thus, while the majority of their business operations may be as retailers, these facilities would, under our understanding of the proposed rule, be required to register with FDA because they also function, in effect, as wholesale outlets. Separately registering each facility would create a significant administrative burden.

Consider the Commonwealth of Pennsylvania, for example. In addition to its wholesale warehouse operations that store product for distribution throughout the state, Pennsylvania operates more than 680 retail stores that sell to restaurants, bars and other state-licensed establishments. Thus, Pennsylvania would, under FDA's proposal, have to separately register nearly 700 facilities. Such a requirement would work a severe administrative burden on state government for no apparent gain. In addition, during the course of a year, the state changes the location of some 20-30 facilities, either opening new stores or moving existing locations.

Across the country, many other "control" jurisdictions would face similar burdens. In North Carolina, for instance, the state operates as the single wholesaler of distilled spirits, but the retail operations – again, those that sell to licensees and end-used consumers – are owned and operated by more than 150 county and municipal governments. Each would have to separately register their facilities under the pending proposal.

The solution to this burden is, we submit, obvious. If FDA proceeds with its facility registration requirement – and we have previously indicated our belief that in the case of alcohol beverages such a requirement is duplicative and therefore unnecessary – NABCA strongly urges that the final rule contain a provision permitting the owner or operator of multiple facilities the flexibility to register each facility separately, or, alternatively, to submit one registration statement listing all covered facilities.

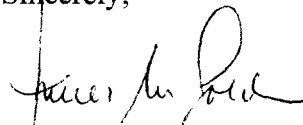
FDA, if it desired, could still assign separately registration numbers to each facility. But in the case of Pennsylvania and the other control jurisdictions, the administrative burden would be significantly reduced if the state had the option to submit basic ownership information one time accompanied by a listing of the address and other identification of all covered facilities.

There is another area of control state operations that the final rules should address. As indicated previously, many control states operate their retail outlets through what is called an "agency" system. The outlet may be a convenience store, grocery store or other retail facility that is owned by a private individual or company. With regard to alcohol beverage distribution, however, the retail operator functions as an "agent" of the state, i.e., the state maintains ownership of the alcohol beverage products being sold and dictates the retail price at which they will be sold to the general public and to licensees such as restaurants and bars.

It is clear that the proposed regulations would require the facility to be registered because it sells to other than end-use consumers. The unresolved issue, however, is who is required to register. Is it the state, which maintains ownership of the product, or the private retailer who operates the store? NABCA submits that this issue should be clarified in final regulations to make clear where the registration responsibility lies. If it is with the state, this provides yet another reason why the alternative of multiple registration rather than merely separate registration should be allowed.

NABCA would be happy to meet with appropriate FDA staff personnel to discuss these issues in greater detail, should the agency feel that such a meeting would be helpful in the formulation of the final rule.

Sincerely,



James M. Goldberg